

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**INDIVIOR INC., INDIVIOR UK
LIMITED, and AQUESTIVE
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**DR. REDDY’S LABORATORIES S.A.,
AND DR. REDDY’S LABORATORIES,
INC.,**

Defendants.

Civ. No. 17-7111 (KM) (CLW)

Civ. No. 18-1775 (KM) (CLW)

Civ. No. 18-5288 (KM) (CLW)

**INDIVIOR INC., INDIVIOR UK
LIMITED, and AQUESTIVE
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**ALVOGEN PINE BROOK, INC., AND
ALVOGEN PINE BROOK LLC,**

Defendants.

Civ. No. 17-7106 (KM) (CLW)

Civ. No. 18-8285 (KM) (CLW)

OPINION

KEVIN MCNULTY, U.S.D.J.:

These consolidated patent infringement cases are brought by Indivior Inc., Indivior UK Limited (collectively, “Indivior”), and Aquestive Therapeutics, Inc. (“Aquestive”), against Dr. Reddy’s Laboratories S.A. and Dr. Reddy’s Laboratories, Inc. (collectively, unless otherwise specified, “DRL”) and Alvogen Pine Brook, Inc. and Alvogen Pine Brook LLC (collectively, unless otherwise specified, “Alvogen”).

The patents-in-suit are Patent Nos. 9,931,305 (“the ’305 Patent”), issued to Aquestive on April 3, 2018, and 9,687,454 (“the ’454 Patent”), issued to Indivior on June 27, 2017. Indivior’s Suboxone film is also covered by Patent No. 8,603,514 (“the ’514 Patent”). The ’514 Patent shares the same specification with the ’305 Patent. As a result, the ’305 Patent was filed with a terminal disclaimer to synchronize its expiration with that of the ’514 Patent. Likewise, the ’454 Patent shares the same specifications with another patent, U.S. Patent No. 8,475,832 (“the ’832 Patent”). This ’514 Patent and the ’832 Patent are not directly at issue here, but were at issue in a related litigation involving similar parties filed in the United States District Court for the District of Delaware (“the Delaware Litigation”).

Collectively, these patents describe formulations of Suboxone film¹, a “rapidly dissolving film that adheres to the underside of a patient’s tongue” or cheek. Indivior’s Suboxone film is used to treat opioid dependency; it works to decrease a patient’s need for opioids while also deterring abuse. Defendants are manufacturers and developers of generic competitors to Suboxone film.

This matter has been extensively litigated for a number of years. Currently before the Court are several motions: (1) Plaintiffs’ appeal of Magistrate Judge Waldor’s Opinion and Order granting Defendants’ motion to amend their answer to add counterclaims; (2) Aquestive’s motion to dismiss Alvogen’s and DRL’s counterclaims; and (3) Defendants’ motion for a Rule 54(b) entry of a partial final judgment of noninfringement.²

For the reasons outlined herein, I will:

1. **Deny** Plaintiffs’ appeal of Judge Waldor’s Opinion and Order;
2. **Deny** Aquestive’s motion to dismiss; and

¹ Suboxone film is Plaintiffs’ brand name for co-formulated buprenorphine/naloxone sublingual film.

² I am also in receipt of a number of letters filed in both actions (*See, e.g.*, 7106 Action, DE 316, 318, 319) concerning these motions and whether to administratively terminate certain motions in favor of granting Plaintiffs leave to file a motion for summary judgment. These scheduling matters will be referred to the Magistrate Judge for decision.

3. **Deny** Defendants' motion for a Rule 54(b) entry of partial final judgment.

I. Relevant Procedural History³

I write for the parties and assume they are familiar with the key facts of this matter. Nevertheless, I will first briefly review the relevant procedural history surrounding the litigation of the at-issue patents, both in this district and elsewhere.

In 2014, Indivior's predecessor, Reckitt Benckiser, brought suit in the District of Delaware against a number of parties alleging infringement of several patents, including the '832 Patent and the '514 Patent. After two bench trials, the Delaware district court held that Indivior had failed to meet its burden of showing that DRL's and Alvogen's generic versions infringed the claims of the '514 Patent for Suboxone film and found the '832 patent invalid for obviousness and indefiniteness. *Reckitt Benckiser Pharm. Inc. v. Watson Labs., Inc.*, No. CV 13-1674-RGA, 2016 WL 3186659, at *27 (D. Del. June 3, 2016); *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, Nos. 14-1451, 14-1573, 14-1574, 2017 WL 3837312 (D. Del. Aug. 31, 2017); *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, No. CV 14-1451-RGA, 2017 WL 3782782

³ Citations to the record will be abbreviated as follows. Citations to page numbers refer to the page numbers assigned through the Electronic Court Filing system, unless otherwise indicated:

"DE" = Docket entry number in this case.

"7106 Action" = Civil Action No. 2:17-cv-7106-KM-CLW.

"7111 Action" = Civil Action No. 2:17-cv-7111-KM-CLW.

"305 Patent" = United States Patent No. 9,931,305, Pl. Ex. A (Dkt. No. 7106 at DE 135-1; Dkt. No. 7111 at DE 250-1).

"454 Patent" = United States Patent No. 9,687,454, Pl. Ex. B (Dkt. No. 7106 at DE 135-1; Dkt. No. 7111 at DE 250-1).

"514 Patent" = United States Patent No. 8,603,514, Pl. Ex. C (Dkt. No. 7106 at DE 135-1; Dkt. No. 7111 at DE 250-1).

"832 Patent" = United States Patent No. 8,475,832.

(D. Del. Aug. 31, 2017); *Indivior Inc. v. Mylan Techs. Inc.*, 298 F. Supp. 3d 775 (D. Del. 2018). Indivior then appealed to the Federal Circuit.

While the Delaware Litigation was proceeding, in 2016, dozens of states filed antitrust lawsuits against Indivior concerning its Suboxone products.

Plaintiffs responded to the Delaware rulings by applying for two additional patents. First, the '454 Patent issued to Indivior on June 27, 2017. Second, the '305 Patent⁴ issued to Aquestive on April 3, 2018. Following the issuance of these patents, on September 14, 2017, Plaintiffs filed the 7106 and 7111 Actions, alleging infringement of the '454 Patent.⁵ On April 3, 2018, Plaintiffs then filed suit against DRL and Alvogen claiming infringement of the new '305 Patent. (*See* 2:18-cv-5288 at DE 1; 2:18-cv-5285 at DE 1). Ultimately all of these actions were consolidated.

Upon learning of DRL's plans to launch the ANDA product "at risk," in June 2018 Indivior moved to enjoin DRL from bringing its generic Suboxone film to market. (7111 Action at DE 70, 71)

On July 13, 2018, I granted the motion for a preliminary injunction, believing that Indivior had successfully "claimed around" the problem that produced the Delaware rulings. (*Id.* at DE 121). DRL then appealed to the Federal Circuit, which disagreed. On November 20, 2018, the Federal Circuit, over a dissent, reversed and remanded, finding that Indivior was unlikely to succeed on the merits of its infringement claim. *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 752 F. App'x 1024 (Fed. Cir. 2018) ("*Indivior I*").

Meanwhile, on January 22, 2019, Indivior moved in this Court for temporary restraints and a preliminary injunction to prevent Alvogen from launching its generic product prior to the Federal Circuit's issuance of its mandate in *Indivior I*. (7106 Action at DE 83). I granted a temporary restraining

⁴ The '514 Patent and the '305 Patent largely overlap, except as to the language of one claim—Claim 26 of the '305 Patent and Claim 62 of the '514 Patent.

⁵ The '832 Patent and the '454 Patent have the same specifications, but the '454 Patent is directed to a bioequivalent film version of Suboxone tablets.

order (“TRO”) enjoining Alvogen from launching in order to preserve the status quo pending the issuance of the mandate. (*Id.* at DE 88)

On February 4, 2019, the Federal Circuit denied rehearing in *Indivior I*. On February 19, 2019, the Federal Circuit issued its mandate vacating the DRL preliminary injunction. The same day, I vacated the injunctive restraints. (*Id.* at DE 119). DRL and Alvogen then proceeded to bring to market their generic versions of Suboxone films.

On April 9, 2019, the Department of Justice announced that Indivior had been indicted for “engaging in an illicit nationwide scheme to increase prescriptions of Suboxone Film, an opioid drug used in the treatment of opioid addiction.” *U.S. v. Indivior Inc. et al*, No. 19-cr-16 (W.D. Va. Apr. 9, 2019).

On July 11, 2019, the U.S. Federal Trade Commission (“FTC”) filed a complaint against Indivior alleging anticompetitive conduct. *F.T.C. v. Reckitt Benckiser Group PLC et al*, No. 19-28 (W.D. Va. July 11, 2019).

On July 12, 2019, the Federal Circuit, issued its opinion on the appeals taken in the Delaware Litigation. In this opinion, here deemed *Indivior II*, the Federal Circuit largely upheld the Delaware district court’s findings. *Indivior Inc. v. Dr. Reddy’s Labs., S.A.*, 930 F.3d 1325, 1339 (Fed. Cir. 2019) (“*Indivior II*”). In analyzing the ’514 Patent in *Indivior II*, the Federal Circuit made clear that for these purposes, the claims of the ’305 Patent are indistinct from those of the ’514 Patent.

On November 5, 2019, I entered an Opinion construing key terms of the patents in suit here following a *Markman* hearing. (7106 Action at DE 215; 7111 Action at DE 294)

On November 19, 2019, Judge Waldor issued an Opinion and Order permitting Alvogen and DRL to file their first amended answer with affirmative defenses and counterclaims. (7106 Action at DE 217; 7111 Action at DE 296)

DRL’s first amended answer asserts two counterclaims:

Count 1: Monopolization and Conspiracy to Monopolize in violation of Section 2 of the Sherman Act; and

Count 2: Recovery of Damages for wrongful injunction against sureties.

(7111 Action at DE 218)

Alvogen's answer asserts two counterclaims:

Count 1: Monopolization and Conspiracy to Monopolize in violation of Section 2 of the Sherman Act; and

Count 2: Monopolization and Conspiracy to Monopolize in violation of the New Jersey Antitrust Act.

(7106 Action at DE 297)

On December 4, 2019, Plaintiffs filed an appeal of Judge Waldor's Opinion and Order to this Court. Defendants oppose the appeal. (7106 Action at DE 220, DE 229; 7111 Action at DE 300, DE 311)

On January 9, 2020, I so-ordered the parties' stipulation of non-infringement as to the '305 Patent. (7106 Action at DE 240; 7111 Action at DE 323) The stipulation was entered subject to the parties' reservation of rights on appeal.

On January 17, 2020, Aquestive then moved to dismiss Defendants' counterclaims. (7106 Action at DE 250; 7111 Action at DE 330) Indivior did not join in this motion and instead filed an answer to the counterclaims. (7106 Action at DE 251; 7111 Action at DE 331)

On January 21, 2020, DRL moved for entry of partial judgment under Rule 54(b) in the 7111 Action. (DE 334) Three days later, on January 24, 2020, Alvogen filed a similar motion. (DE 261)

II. Appeal of Ruling on Motion to Amend and Motion to Dismiss

Because of the largely overlapping issues presented by Plaintiffs' appeal and by Aquestive's motion to dismiss, I will address these motions together in Section II of this Opinion. I will separately address Defendants' motion for partial judgment under Rule 54(b) in Section III.

A. Applicable Standards

i. Standard of Review of a Magistrate Judge's Decision

If a party objects to a magistrate judge's order regarding a nondispositive matter, the district court "must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law." *Id.*; 28 U.S.C. §

636(b)(1)(A). This standard requires the District Court to review findings of fact for clear error and to review matters of law *de novo*. *Haines v. Liggett Grp. Inc.*, 975 F.2d 81, 91 (3d Cir. 1992).

Equal Employment Opportunity Comm’n v. City of Long Branch, 866 F.3d 93, 99 (3d Cir. 2017). *See also* Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A). This Court has frequently spoken of the discretion granted to the Magistrate Judge in non-dispositive matters. Where the appeal seeks review of a matter within the core competence of the Magistrate Judge, such as a discovery dispute, the court will defer to the Magistrate Judge’s discretion. *See Cooper Hospital/Univ. Med. Ctr. v. Sullivan*, 183 F.R.D. 119, 127 (D.N.J. 1998); *Deluccia v. City of Paterson*, No. 09-703, 2012 WL 909548, at *1 (D.N.J. March 15, 2012). “This deferential standard is especially appropriate where the Magistrate Judge has managed this case from the outset and developed a thorough knowledge of the proceedings.” *Lithuanian Commerce Corp., Ltd. v. Sara Lee Hosiery*, 177 F.R.D. 205, 214 (D.N.J. 1997) (internal quotations omitted); *see Deluccia*, 2012 WL 909548, at *1 (same).⁶

A report and recommendation on a dispositive issue, though, requires plenary review:

The product of a magistrate judge, following a referral of a dispositive matter, is often called a “report and recommendation.” Parties “may serve and file specific written objections to the proposed findings and recommendations” within 14 days of being served with a copy of the magistrate judge’s report and recommendation. Fed. R. Civ. P. 72(b)(2). If a party objects timely to a magistrate judge’s report and recommendation, the district court must “make a *de novo* determination of those portions of the report or specified proposed findings or recommendations to which objection is made.” 28 U.S.C. § 636(b)(1); *see also* Fed. R. Civ. P. 72(b)(3).

⁶ The standard of review of nondispositive matters has sometimes been referred to as abuse of discretion. As a practical matter, it makes little difference, because abuse-of-discretion review incorporates plenary review of legal questions and clear-error review of factual questions. *See Koon v. United States*, 518 U.S. 81, 100 (1996) (a court “by definition abuses its discretion when it makes an error of law”); *Doeblers’ Pennsylvania Hybrids, Inc. v. Doeblers*, 442 F.3d 812, 819 (3d Cir. 2006) (abuse of discretion may encompass “a clearly erroneous finding of fact, an errant conclusion of law, or an improper application of law to fact”).

Equal Employment Opportunity Comm’n v. City of Long Branch, 866 F.3d at 99–100.

A dispositive motion, if denied, is in a trivial sense non-dispositive. Still, these particular motions were potentially dispositive, not of a routine amendment, but of the addition of new and significant counterclaims not previously available. Thus, in an abundance of caution, I give Judge Waldor’s decision, and the motion to dismiss, *see infra*, the same plenary level of review.

ii. Motion to Dismiss Standard

Federal Rule of Civil Procedure 8(a) does not require that a complaint contain detailed factual allegations. Nevertheless, “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitlement to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 232 (3d Cir. 2008) (Rule 8 “requires a ‘showing’ rather than a blanket assertion of an entitlement to relief.” (citation omitted)). Thus, the complaint’s factual allegations must be sufficient to raise a plaintiff’s right to relief above a speculative level, so that a claim is “plausible on its face.” *Twombly*, 550 U.S. at 570; *see also West Run Student Hous. Assocs., LLC v. Huntington Nat. Bank*, 712 F.3d 165, 169 (3d Cir. 2013).

That facial-plausibility standard is met “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While “[t]he plausibility standard is not akin to a ‘probability requirement’ . . . it asks for more than a sheer possibility.” *Id.*

Rule 12(b)(6) provides for the dismissal of a complaint if it fails to state a claim upon which relief can be granted. The defendant, as the moving party, bears the burden of showing that no claim has been stated. *Animal Science Products, Inc. v. China Minmetals Corp.*, 654 F.3d 462, 469 n.9 (3d Cir. 2011). For the purposes of a motion to dismiss, the facts alleged in the complaint are

accepted as true and all reasonable inferences are drawn in favor of the plaintiff. *New Jersey Carpenters & the Trustees Thereof v. Tishman Const. Corp. of New Jersey*, 760 F.3d 297, 302 (3d Cir. 2014).

For the purposes of a motion to dismiss, the facts alleged in the counterclaim-complaint are accepted as true and all reasonable inferences are drawn in favor of the plaintiff. *New Jersey Carpenters & the Trustees Thereof v. Tishman Const Corp. of New Jersey*, 760 F.3d 297, 302 (3d Cir. 2014).

B. Discussion

i. The Appeal and Motion to Dismiss⁷

Plaintiffs appeal from Magistrate Judge Waldor's November 19, 2019 decision (DE 217) granting Defendants' motion to file a first amended answer with counterclaims pursuant to Fed. R. Civ. P. 72(a) and Local Rule 72.1(c). As to the antitrust counterclaims, Aquestive also moves to dismiss. For the reasons stated herein, I will affirm Magistrate Judge Waldor's decision and deny the motion to dismiss. Subsection 1 addresses DRL's wrongful-injunction counterclaim; subsection 2 addresses the antitrust arguments.

1. DRL's Second Counterclaim

As part of its amended answer, DRL asserts a second counterclaim seeking to recover damages from a Surety for a wrongful injunction. (7111 Action, DE 297 at 67) Plaintiffs assert that DRL lacks Article III standing to assert such a claim. DRL's injury, they say, is not actual because it is based on speculation that Indivior will be unable to satisfy any final judgment against it. (DE 220-1 at 23-25) Plaintiffs add that the wrongfulness, or not, of the injunction cannot be determined until there is a final judgment.

DRL responds that it has standing to pursue its claims based on the numerous rulings in this case, *Indivior I*, and *Indivior II*. (DE 229 at 24-25) The parties moreover have stipulated that DRL did not infringe the '305 Patent.

⁷ Because identical briefing was filed in both actions, unless otherwise indicated, I will refer to the docket entry numbers for the briefing filed in the 7106 Action throughout Section II of this Opinion.

That is enough, says DRL, to establish that it was wrongfully enjoined and is entitled to recover under the bond. I agree, at least insofar as the claims as to the '305 Patent have been finally decided. (See 7106 Action at DE 240; 7111 Action at DE 323)

Rule 65 allows a successful defendant to collect on a bond if it is “found to have been wrongfully enjoined or restrained.” Fed. R. Civ. P. 65(c); *Atomic Oil Co. of Okl. v. Bardahl Oil Co.*, 419 F.2d 1097, 1101 (10th Cir. 1969) (“Rule 65(c) creates a cause of action for the costs and damages incurred by the enjoined party should it later be determined that that party was wrongfully enjoined or restrained.”).⁸ Indeed, that is the purpose of posting a bond. The Third Circuit has held that Rule 65(c) “strongly implies” that a prevailing defendant is entitled to damages on the injunction bond, and has adopted the stance of the “clear majority of our sister circuits” that “have held that there is a rebuttable presumption that a wrongfully enjoined party is entitled to recover provable damages up to the bond amount.” *Nat’l Collegiate Athletic Ass’n v. Governor of New Jersey*, 939 F.3d 597, 606-07 (3d Cir. 2019), *cert. denied*, 206 L. Ed. 2d 938 (May 18, 2020). As I held in connection with the *Markman* Opinion, however, “[i]t is settled that one can recover on an injunction bond only after a trial and final judgment on the merits.” *Clark v. K-Mart Corp.*, 979 F.2d 965, 969 (3d Cir. 1992); *Nat’l Collegiate Athletic Ass’n*, 939 F.3d at 605 (confirming in the context of TRO that “whether a party was wrongfully enjoined depends upon the final judgment on the merits”). Only an adverse final judgment definitively establishes that a party was wrongfully enjoined in the interim. Accordingly, should a final judgment establish that DRL was wrongfully enjoined, it is presumptively entitled to recover on the injunction bond.

⁸ The full text of Rule 65(c) reads: “The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained. The United States, its officers, and its agencies are not required to give security.”

In a sense, DRL's counterclaim, considered as such, is therefore superfluous. Nevertheless, DRL can choose what claims to bring, and it appears that courts have permitted such claims to be pled independently. The elements of a claim for recovery on a bond posted pursuant to Rule 65(c) of the Federal Rules of Civil Procedure are "(1) existence of the bond; (2) wrongful issuance of the restraining order; and (3) damage to the restrained party resulting from the restraining order." *Qualcomm, Inc. v. Motorola, Inc.* 185 F.R.D. 285, 287 (S.D. Cal. 1999) (citing *Buddy Systems, Inc. v. Exer-Genie, Inc.*, 545 F.2d 1164, 1169 n. 10 (9th Cir. 1976), *cert. denied*, 431 U.S. 903 (1977)). Here, DRL has pled facts that sufficiently establish all three elements. Elements 1 and 3 are not controversial: A bond has been posted, and DRL has plausibly alleged damages as a result of being prohibited from entering the generic market.

As for Element 2, however, it remains to be finally determined whether DRL was wrongfully enjoined as to all claims at issue here. It is true, of course, that the preliminary injunction has been dissolved. It is also true that a final determination of wrongfulness and entitlement to recovery must await entry of a final judgment. Something similar might be said, however, of virtually any claim a party might assert in a complaint; it does not undermine standing or require dismissal of a claim that is plausibly asserted.

Accordingly, I will deny Plaintiffs' appeal (7106 Action at DE 220; 7111 Action at DE 300) of Judge Waldor's Opinion and Order insofar as it seeks to overturn the decision to permit DRL to assert its second counterclaim for recovery under the bond.

ii. Antitrust Arguments

As to the antitrust counterclaims, Plaintiffs' appeal from Judge Waldor's Opinion and Aquestive's motion to dismiss present overlapping arguments, which I address together. For the reasons stated below, I will affirm Judge Waldor's Opinion permitting Defendants to assert antitrust counterclaims, and

deny Aquestive's motion (7106 Action at DE 250; 7111 Action at DE 330) to dismiss them.

1. Section 2 of the Sherman Act

"The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Queen City Pizza v. Domino's Pizza*, 124 F.3d 430, 437 (3d Cir. 1997) (quoting *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 596 n. 19 (1985)). An attempted monopolization claim has three elements: "a plaintiff must prove that the defendant (1) engaged in predatory or anticompetitive conduct with (2) specific intent to monopolize and with (3) a dangerous probability of achieving monopoly power." *Id.* at 442. Under either section 1 or 2, the plaintiff bears the burden of pleading the relevant geographic and product markets. *Id.* at 436-37.

A patentee can attempt to establish element 1, predatory or anticompetitive conduct, by pleading facts that establish "(1) that the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965), or (2) that the infringement suit was 'a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor. *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).'" *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed. Cir. 1998) (additional internal citations omitted)).

The "sham litigation" theory is the one at issue here.⁹ Defendants allege that Indivior's patent litigation was part of an anticompetitive scheme.

⁹ Alvogen additionally asserts a second counterclaim for violations of the New Jersey Antitrust Act. New Jersey's Antitrust Act is essentially a replica of the federal Sherman Antitrust Act, *see, e.g.*, N.J. Stat. § 56:9-1, *et seq.*, and must be interpreted in accordance with federal antitrust principles. "This act shall be construed in

A Section 2 conspiracy claim, like the one Defendants assert against Aquestive, has four elements: (1) an agreement to monopolize; (2) an overt act in furtherance of the conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged.” *Howard Hess Dental Labs. Inc. v. Dentsply Int’l, Inc.*, 602 F.3d 237, 253 (3d Cir. 2010).

2. Noerr-Pennington Doctrine¹⁰

Any antitrust claim based on a party’s pursuit of litigation must negotiate the potential bar of the *Noerr-Pennington* doctrine. “Rooted in the First Amendment and fears about the threat of chilling political speech,” the *Noerr-Pennington* doctrine provides immunity from antitrust liability for parties who petition the government for redress. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 264 (3d Cir. 2017) (quoting *AD. Bedell Wholesale Co. v. Phillip Morris Inc.*, 263 F.3d 239, 250 (3d Cir. 2001)). The doctrine extends to “actions which might otherwise violate the Sherman Act because ‘[t]he federal antitrust laws do not regulate conduct of private individuals in seeking anticompetitive action from the government.” *Id.* More broadly, “[g]overnment advocacy is protected by *Noerr-Pennington* immunity; seeking governmental approval of a private agreement is not.” *Id.* The scope of *Noerr-Pennington* immunity depends on the source, context, and nature of the competitive restraint at issue. *Id.* *Noerr-Pennington* has been extended to provide immunity to private efforts to influence courts and agencies, whether federal or state, *Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606, 611 (D.N.J. 2000), and has been held to shield plaintiffs from liability for pursuing state common law claims such as

harmony with ruling judicial interpretations of comparable Federal antitrust statutes and to effectuate, insofar as practicable, a uniformity in the laws of those states which enact it.” N.J. Stat. Ann. § 56:9-18. Accordingly, my analysis in Section II.B.ii additionally applies to Alvogen’s counterclaim asserting violations of the New Jersey Antitrust Act.

¹⁰ The titular cases are *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).

tortious interference with contract and tortious interference with prospective economic gain. *Santana Products, Inc. v. Bobrick Washroom Equipment, Inc.*, 401 F.3d 123, 140 (3d Cir. 2005) (declining to decide whether a marketing campaign is petitioning activity that could be immunized by the doctrine).

However, *Noerr-Pennington* is not an absolute shield that covers all litigation and petitioning activity. *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 178 (3d Cir. 2015). The immunity ends where the litigation “is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor and the application of the Sherman Act would be justified.” *Id.* (quoting *Noerr Motor Freight, Inc.*, 365 U.S. at 144). In determining whether litigations are a sham, the Third Circuit has adopted the approach that governs in the Second, Fourth, and Ninth Circuits when applying *California Motor Transportation Co. v. Trucking Unlimited*, 404 U.S. 508 (1972) and *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993). See *Hanover 3201 Realty, LLC*, 806 F.3d at 180. First, the court must determine whether there has been a single filing or a series of filings. *Id.* If there has been just a single filing, there must be “a showing of objective baselessness before looking into the subjective motivations” of the party alleged to have engaged in anti-competitive behavior. *Id.* (noting that *Professional Real Estate*’s “exacting two-step test” puts a heavy thumb on the scale in favor of the party who has had a claim made against it). On the other hand, when faced with a “series or pattern of lawsuits,” a more flexible approach is warranted. *Id.* In that scenario, even if some of the petitions turn out to have objective merit, the claimant is not automatically immunized from liability. *Id.*

A court may decide the applicability of the *Noerr-Pennington* doctrine on a motion to dismiss under Fed. R. Civ. P. 12(b)(6) if no factual issues are present. *Trustees of Univ. of Pa. v. St. Jude Children’s Res. Hosp.*, 940 F. Supp. 2d 233, 242–43 (E.D. Pa. 2013) (“To be sure, the question of whether litigation is a sham can be a fact question for the jury. But as the Supreme Court

explained in PRE, when there is no dispute over the predicate facts of the underlying legal proceeding, a court may decide probable cause [and thus *Noerr-Pennington* applicability] as a matter of law.” (citations omitted and emphasis added)); *Asphalt Paving Sys. v. Asphalt Maint. Sols., LLC*, No. 12–2370, 2013 WL 1292200, at *7–*8 (E.D. Pa. Mar. 28, 2013) (deciding only that *Noerr-Pennington* immunity applied in its grant of dismissal); *Bristol-Myers Squibb Co. v. WAX Corp.*, 77 F. Supp. 2d 606, 616 (D.N.J. 2000) (same.).

As Chief Judge Wolfson recently noted when surveying cases in this district, the issue is a fact-intensive one, generally not suitable for resolution at the pleading stage:

Notably, district courts within this Circuit have routinely prohibited parties from invoking the protections of *Noerr-Pennington* at the dismissal stage of a case in the context of patent suits, at which time the factual record remains undeveloped and insufficient for the purpose of determining whether a “sham litigation” has been filed. *FTC v. Shire ViroPharma, Inc.*, No. 17-131, 2018 WL 1401329, at *7, 2018 U.S. Dist. LEXIS 45727, at *18 (D. Del. March 20, 2018) (“[W]hether [the patent holder's] activity was in fact a sham under either standard is a factual inquiry, which cannot be resolved at the motion to dismiss stage.”); *Otsuka Pharm. Co.*, 118 F.Supp.3d at 657 (“Moreover, even assuming the allegations proved insufficient, the inquiry into whether [the plaintiff-counter-defendant] maintains in this action ‘objectively and subjectively baseless’ infringement claims turns upon issues of reasonableness and intent—issues which are premature to consider upon the present record.”); *S3 Graphics Co. v. ATI Techs. ULC*, No. 11-1298, 2014 WL 573358, at *3, 2014 U.S. Dist. LEXIS 16928, at *9 (D.N.J. Feb. 11, 2014) (holding that the issue of *Noerr-Pennington* immunity is “not proper before discovery”); *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 3860680, at *6, 2011 U.S. Dist. LEXIS 98547, at *6 (D. Del. Aug. 31, 2011) (“Whether the underlying litigation is baseless is a factual issue not to be determined on a motion to dismiss.”); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, No. 06-52, 2010 WL 1485328, at *10, 2010 U.S. Dist. LEXIS 36303, at *34 (D. Del. April 13, 2010) *395 (“The court, however, cannot [determine whether *Noerr-Pennington* applies] at the motion to dismiss stage, because it is fact intensive”); *Hoffman La Roche Inc. v. Genpharm Inc.*, 50 F.Supp.2d 367, 380 (D.N.J. 1999) (“Reasonableness is a question of fact, and the Court cannot make such factual determinations on a factual controversy roiled by a motion to dismiss.”).

Takeda Pharm. Co. Ltd. v. Zydus Pharm. (USA) Inc., 358 F. Supp. 3d 389, 394–95 (D.N.J. 2018).

3. Analysis of the Antitrust Claims

a. Appeal

On appeal, Plaintiffs (as counterclaim defendants) argue that Judge Waldor’s Opinion and Order contained clear error. (DE 220) Plaintiffs assert that, under *Noerr-Pennington*, their actions here—particularly, filing these Hatch-Waxman suits and obtaining preliminary injunctions—are presumptively shielded from antitrust liability. The facts pled, in Defendants’ view, are not sufficient to overcome this presumption, and Judge Waldor should have rejected any claim based on the narrow “sham litigation” exception to the *Noerr-Pennington* Doctrine. (*Id.* at 6) At this, the pleading stage, I must disagree.

I pause briefly to consider the threshold issue of the timeliness of this amendment, which was asserted after the deadline to amend pleadings. Rule 16 imbues Magistrate Judges with wide discretion in determining whether “good cause” to warrant amendment has been presented.¹¹ Judge Waldor cited the discovery of emails and documents attached to the Indivior Indictment, which came to light after the deadline to amend pleadings. (DE 217 at 4) I agree with Judge Waldor that there was good cause to permit a belated amendment.

Judge Waldor then turned to the substance of whether the Rule 15 motion to amend should be granted. Plaintiffs argued before Judge Waldor, and continue to do so in their motion here, that the sham litigation exception to

¹¹ Recent Third Circuit guidance confirms the aptness of Judge Waldor’s approach. Before considering whether Rule 15’s standard for amendment governed, Judge Waldor appropriately considered whether Defendants’ motion met Rule 16’s more demanding requirements. “When a party moves to amend or add a party after the deadline in a district court’s scheduling order has passed, the “good cause” standard of Rule 16(b)(4) of the Federal Rules of Civil Procedure applies. A party must meet this standard before a district court considers whether the party also meets Rule 15(a)’s more liberal standard.” *Premier Comp Sols., LLC v. UPMC*, No. 19-1838, 2020 WL 4668235, at *2 (3d Cir. Aug. 12, 2020).

Noerr-Pennington had not been adequately pled and that Defendants' amendments should therefore be rejected as futile. (DE 217 at 5) Judge Waldor rejected these arguments and I do as well.

"Futility," in this context, means that the proposed amended complaint "would not withstand a motion to dismiss." *Massarsky v. Gen. Motors Corp.*, 706 F.2d 111, 125 (3d Cir. 1983); *see also Brown v. Philip Morris Inc.*, 250 F.3d 789, 796 (3d Cir. 2001); *Jablonski*, 863 F.2d at 292; *Adams v. Gould Inc.*, 739 F.2d 858, 864 (3d Cir. 1984). Therefore, "[i]n assessing 'futility,' the District Court applies the same standard of legal sufficiency as applies under Rule 12(b)(6)." *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000); *see also* Section II.A.ii, *supra* (motion to dismiss standards). "[I]f the proposed amendment 'is frivolous or advances a claim or defense that is legally insufficient on its face, the court may deny the motion to amend. If a proposed amendment is not clearly futile, then denial of leave to amend is improper.'" *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990).

The analysis therefore merges with the motion to dismiss, discussed in the next section. For the reasons outlined there, Defendants' proposed amendments are not futile, because they would withstand a motion to dismiss.

b. Motion to Dismiss

In moving to dismiss, Aquestive reasserts the "sham litigation" arguments it presented in its appeal of Judge Waldor's decision. (DE 250 at 20) Aquestive adds that Defendants' allegations fail because (1) there are no facts that establish Aquestive is a competitor in the relevant market (MTD Br. at 13-16); (2) the allegations improperly allege a shared monopoly (*Id.* at 16-18); and (3) Defendants efforts at group pleading fail to specifically address Aquestive's individual conduct (*Id.* at 18-19).

First, I reject Plaintiffs' argument that Defendants have failed to sufficiently allege that they engaged in anticompetitive "sham litigation." This is not a case of a single filing. The antitrust allegations in the first instance assert that Plaintiffs' claims were objectively baseless and part of a larger strategic

effort by Plaintiffs to take steps that they knew would delay or inhibit FDA authorization for generic competitors. (*See, e.g.*, 7106 Action, DE 218 ¶¶ 71-74, 87, 90) The counterclaims allege some particulars of that overall strategic anticompetitive effort. For example, “when faced with imminent generic competition, Indivior engaged in an elaborate corporate marketing strategy to mislead physicians and patients in order to eliminate generic competition for its products.” (*Id.* ¶ 106) Moreover, Indivior “fabricated [a] safety story that Suboxone Film was safer, namely that the film would protect against diversion and accidental child exposure as compared to the tablets” to get patients to switch to using the films and to undermine the market for tablets. (*Id.* ¶ 110). Indivior likewise is alleged to have developed a marketing strategy to extend its monopoly power by, for example, increasing the cost of its tablets to encourage patients to switch. (*Id.* ¶¶ 113, 156–66) Aquestive was allegedly part and parcel of this strategy, as it owned the ’305 Patent and agreed with Indivior to continue to file for new patents, then file lawsuits here and elsewhere, which included seeking injunctions based on new patents that were patentably indistinct from the patents at issue in *Indivior II*. (*Id.* ¶¶ 115-145)

Second, the counterclaims assert that Plaintiffs controlled pricing and output of products in that they controlled 100% of the Suboxone market in the US and used this power to harm competition. (*Id.* ¶¶ 196-99) Defendants allege that Plaintiffs, including Aquestive, collectively leveraged their patents to develop marketing and legal strategies that enabled Indivior to manipulate the market for Suboxone products and decrease competition for their Suboxone Film. (*Id.* ¶¶ 196-99)

The patent litigation, the counterclaim asserts, was part of this anticompetitive strategy. Now of course, under *Noerr-Pennington*, it is not enough that the underlying patent claims did not succeed. I expect Plaintiffs will have much to say about the colorable, good faith basis for their patent claims, irrespective of whether they ultimately prevailed. *See, e.g., Takeda, supra*. Two judges have seen things Plaintiffs’ way, at least on certain issues.

But the Defendants have sufficiently alleged that the underlying litigation was baseless and was intended to stifle competition. The rest must await summary judgment or a trial. Accordingly, I find that the allegations in the counterclaims sufficiently plead the sham litigation exception.

In so holding I am mindful that, as this court recently held, “the inquiry into whether [Plaintiff] maintains in this action ‘objectively and subjectively baseless’ infringement claims turns upon issues of reasonableness and intent—issues which are premature to consider upon the present record. Indeed, resolution of these inherently factual issues requires consideration of whether [Plaintiff] undertook a reasonable investigation in advance of pursuing its infringement claims, whether [Plaintiff] undertook this action for an improper and anticompetitive purpose, and whether a reasonable litigant could have realistically expected success on the merits at the time of filing.” *Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc.*, 118 F. Supp. 3d 646, 657 (D.N.J. 2015). None of these issues are ripe for a determination at this stage of the proceedings.

Aquestive’s remaining arguments—(1) that there are no facts that establish Aquestive is a competitor in the relevant market (MTD Br. at 13-16); and (2) that the allegations improperly allege a shared monopoly (*Id.* at 16-18)—fare no better. These arguments address a purported claim that Aquestive had monopoly power in the relevant market. But these arguments are ancillary to Defendants’ claim, which is that Aquestive conspired with Indivior to further Indivior’s monopoly power. It is well established that “a claim of conspiracy to monopolize requires only that a company agree with another company to assist the first in its attempt to monopolize the relevant market.” *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 4910673, at *11 (E.D. Pa. Oct. 30, 2017); *Carpet Grp. Int’l v. Oriental Rug Importers Ass’n, Inc.*, 256 F. Supp. 2d 249, 283 (D.N.J. 2003) (“[T]he proof required to demonstrate a conspiracy to monopolize does not require a proof of market power in a relevant market.”). Defendants assert that Aquestive helped conspire with Indivior to impermissibly protect Indivior’s market power and

monopoly. Aquestive contributed to this conspiracy by applying for new patents, filing lawsuits and multiple motions in conjunction with Indivior, and by manufacturing the film for Indivior to then market. (*See, e.g.*, 7111 Action, DE 297 ¶¶ 17, 82, 96-99, 266-67) These allegations are sufficient to establish a claim for conspiracy to monopolize at the motion to dismiss stage.

Accordingly, Aquestive's motion to dismiss Defendants' antitrust claims is denied.

III. Motion for a Rule 54(b) Entry of Partial Final Judgment

In the 7111 Action, DRL moved for an entry of final partial judgment of non-infringement as to the '305 Patent. (7111 Action at DE 334) Alvogen then joined in the motion (7106 Action at DE 261), which Plaintiffs oppose. (7111 Action at DE 350)

Generally, an order which terminates fewer than all claims, or claims against fewer than all parties to an action, does not constitute a "final" decision for purposes of 28 U.S.C. § 1291. Under Rule 54(b), however, a district court may convert such a partial order to a final decision over which a court of appeals may then exercise jurisdiction.

Federal Rule 54(b) provides as follows:

When an action presents more than one claim for relief—whether as a claim, counterclaim, crossclaim, or third-party claim—or when multiple parties are involved, the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay. Otherwise, any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities.

Fed. R. Civ. P. 54(b). Certification under Rule 54(b) is the exception, not the norm. "Not all final judgments on individual claims should be immediately appealable, even if they are in some sense separable from the remaining unresolved claims. The function of the district court under the Rule is to act as a 'dispatcher.' It is left to the sound judicial discretion of the district court to

determine” when an action may be certified as final. *Curtiss–Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 8-9 (1980) (citations omitted). “The power which this Rule confers upon the trial judge should be used only in the infrequent harsh case as an instrument for the improved administration of justice and the more satisfactory disposition of litigation in the light of the public policy indicated by statute [28 U.S.C. § 1291] and rule.” *Panichella v. Pa. R.R. Co.*, 252 F.2d 452, 455 (3d Cir.1958).

The Supreme Court has set forth the steps a court must take in making determinations under Rule 54(b). First, a district court must determine that it is dealing with a “final judgment” as to the particular claim at issue. “It must be a ‘judgment’ in the sense that it is a decision upon a cognizable claim for relief, and it must be ‘final’ in the sense that it is ‘an ultimate disposition of an individual claim entered in the course of a multiple claims action.’” *Curtiss–Wright*, 446 U.S. at 7 (quoting *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427 (1956)). Having made a finding of finality, the court must then determine whether there is “any just reason for delay.” *Id.* at 8.

Here, there appears to be no dispute that there has been a final resolution (subject to appeal, of course) of the claims concerning the ’305 Patent. Indeed, Plaintiffs have entered into a stipulated judgment that Defendants did not infringe the ’305 Patent as construed in my *Markman* Opinion and Order. (See 7111 Action at DE 323)

The parties disagree, however, as to whether there is “any just reason” for delaying entry of a Rule 54(b) final judgment on the ’305 claims. “This latter requirement, that a district court ‘must go on to determine whether there is any just reason for delay,’ is not merely formalistic.” *Elliott v. Archdiocese of New York*, 682 F.3d 213, 220 (3d Cir. 2012). The Third Circuit has set forth several factors to be considered when assessing if there is a “just reason for delay” under Rule 54(b):

- (1) the relationship between the adjudicated and unadjudicated claims;

- (2) the possibility that the need for review might or might not be mooted by future developments in the district court;
- (3) the possibility that the reviewing court might be obliged to consider the same issue a second time;
- (4) the presence or absence of a claim or counterclaim which could result in set-off against the judgment sought to be made final;
- (5) miscellaneous factors such as delay, economic and solvency considerations, shortening the time of trial, frivolity of competing claims, expense, and the like.

Berkeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 203 (3d Cir. 2006) (citing *Allis-Chalmers Corp. v. Philadelphia Elec. Co.*, 521 F.2d 360, 364 (3d Cir. 1975)).

Here I find good reason to delay entry of a final judgment as to the '305 Patent claims. Although the Rule 54(b) motion cites case law severing patent claims from antitrust claims, there is here the complicating factor of the yet-unadjudicated claims under the '454 patent. I take the Defendants' point that the claims are separate, but I nevertheless find as a matter of case management that any final judgment should at least await the resolution of all the patent issues.

Factor 1, the relationship between the adjudicated and unadjudicated claims, counsels delay in entry of judgment. "Where the adjudicated and unadjudicated claims share significant similarities, such as involving the same parties, the same legal issues, or the same evidence, Rule 54(b) certification is disfavored." *Ortho-McNeil Pharm., Inc. v. Kali Labs., Inc.*, No. CIV A 02-5707 DMC, 2007 WL 1814080, at *3 (D.N.J. June 20, 2007). The parties focus generally on the overlap between the claims concerning the '305 Patent and the antitrust counterclaims. My concern is more generally with the overlap between the '305 Patent, the '454 Patent, and the antitrust claims, and what would be the most efficient way to resolve these issues. Certainly the parties in the adjudicated and unadjudicated patent claims are identical and the legal and factual issues, while not wholly identical, are intertwined and related. Factual

issues resolved under the '305 Patent overlap with those concerning the remaining claim as to the '454 Patent. My *Markman* Opinion and Order construed the bioequivalence language under claim 1 of the '454 Patent and the “a polyethylene oxide alone or in combination with a hydrophilic cellulosic polymer” language in claims 9, 10, and 11. However, the primary issues and defenses concerning whether DRL's and Alvogen's generic films infringe the '454 Patent will largely overlap with the issues concerning the '305 Patent.

Factors 3 and 4, too, suggest that Rule 54(b) certification should be denied. Certification of the '305 issues would likely result in a piecemeal appeal to the Federal Circuit. If the claims as to the '305 Patent were deemed final and Plaintiff were to appeal, the Federal Circuit would have to evaluate the correctness of the basis for finding the '305 Patent was infringed. Regardless of the outcome of that decision, the parties will inevitably appeal the Court's decision of the issues concerning the '454 Patent and Defendants' counterclaims. This second appeal would involve much of the same evidence and many of the same legal issues as the first appeal. It would be far more efficient for the Federal Circuit to review all of these issues, especially as they relate to the '305 Patent and the '454 Patent, collectively rather than in successive appeals that would turn largely on identical and interrelated facts.

Factor 2 slightly favors entry of a final judgment now. This Court has already issued its definitive *Markman* opinion. Predictions are perilous, but it seems unlikely that resolution of additional issues concerning the '454 Patent or Defendants' antitrust claims would reach back to alter or moot the rulings made thus far as to the '305 Patent.

As to Factor 5, DRL points to the financial burden of being denied the present ability to collect on the outstanding bond. I understand DRL's complaint that it deserves to collect on this bond (I set aside speculative issues concerning a bonded stay pending appeal). This financial prejudice, however, does not differ fundamentally from the usual course of litigation, in which a plaintiff must generally await final judgment to be awarded damages. I note also that DRL has now been allowed to bring their products to market. I

therefore find that the financial cost of delay, though real, does not outweigh the procedural cost of piecemeal appeals that would depend on resolution of similar facts and legal issues.

Accordingly, Defendants' Rule 54(b) motion for entry of partial final judgment as to non-infringement of the '305 Patent is denied. I will, however, deny this motion without prejudice to a renewed application to sever the patent claims from the antitrust counterclaims after the '454 Patent claims are resolved.

IV. Conclusion

For the reasons set forth above, Plaintiffs' appeal of Judge Waldor's December 4, 2019 Opinion and Order permitting Defendants to amend their answer to add counterclaims (7106 Action DE 220; 7111 Action DE 300) is **denied**.

Aquestive's motion to dismiss Defendants' counterclaims (7106 Action DE 250; 7111 Action DE 330) is **denied**.

Defendants' motion for entry of a partial final judgment (7106 Action DE 261; 7111 Action DE 334) is **denied** without prejudice.

An appropriate order follows.

Dated: August 24, 2020

/s/ Kevin McNulty

Kevin McNulty
United States District Judge